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| 800 SYLVAN | AVENUE | KANTAMNENI, SHOBHA | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Applica | tion No. | Applicant(s) | Applicant(s) | |
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| | | 10/003, | 850 | PILLAI ET AL. | | |
| Office Action Summary | | | er | Art Unit | | |
| | | Shobha | Kantamneni | 1617 | | |
| Th Period for Re | e MAILING DATE of this commun | nication appears on t | he cover sheet with the | correspondence a | ddress | |
| A SHORT WHICHEN - Extensions after SIX (6 - If NO perio - Failure to r Any reply r | ENED STATUTORY PERIOD F /ER IS LONGER, FROM THE N of time may be available under the provision:) MONTHS from the mailing date of this com d for reply is specified above, the maximum s pply within the set or extended period for reply eceived by the Office later than three months ent term adjustment. See 37 CFR 1.704(b). | MAILING DATE OF one of 37 CFR 1.136(a). In no munication. It tatutory period will apply and will, by statute, cause the a | FHIS COMMUNICATION Event, however, may a reply be will expire SIX (6) MONTHS from pplication to become ABANDON | DN. timely filed om the mailing date of this NED (35 U.S.C. § 133). | | |
| Status | | | | | | |
| 1)⊠ Res 2a)⊠ This 3)⊡ Sind | ponsive to communication(s) files action is FINAL . ce this application is in conditioned in accordance with the pract | 2b)⊡ This action is for allowance exce | ot for formal matters, p | | e merits is | |
| Disposition o | of Claims | | | | | |
| 4a) 5)⊠ Cla 6)⊠ Cla 7)□ Cla 8)□ Cla | | are withdrawn from o | consideration. | | | |
| 10)☐ The App Rep | specification is objected to by the drawing(s) filed on is/are licant may not request that any objected the drawing sheet(s) including oath or declaration is objected the drawing sheet is objected to be a sheet is objected the drawing sheet | : a) ☐ accepted or ection to the drawing(sg the correction is requ |) be held in abeyance. S uired if the drawing(s) is c | ee 37 CFR 1.85(a). objected to. See 37 C | | |
| Priority unde | r 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 2) Notice of [3] Information | References Cited (PTO-892) Draftsperson's Patent Drawing Review (In Disclosure Statement(s) (PTO/SB/08) S)/Mail Date | PTO-948) | 4) Interview Summa Paper No(s)/Mail 5) Notice of Informa 6) Other: | | | |

Art Unit: 1617

DETAILED ACTION

Applicant's amendment filed on 04/13/2009, wherein independent claims 1, and

5 have been amended, and new claims 13-16 have been added.

The rejection of claims 1-2, 5-6, and 9-10 on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-2 of U.S.

Patent No. 6565864, in view of Granger et al. (US 5,723,139) is herein withdrawn. Note

that applicant has provided terminal disclaimer.

Applicant's arguments have been considered, but not found persuasive. The

rejection of claims 1, 2, 5, 6, and 9 under 35 U.S.C. 103(a) as being unpatentable over

Granger et al. (US 5,723,139, PTO-892 of record) and Gorbach (WO 98/56373, PTO-

892), in view of Liu et al. (5,976,555, PTO-892 of record), and Suares et al. (US

5,914,116, PTO-1449 of record) is MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive. The

rejection of claims 1, 2, 5, 6, and 9-10 under 35 U.S.C. 103(a) as being unpatentable

over Granger et al. (US 5,723,139, PTO-892), Gorbach (WO 98/56373, PTO-892), and

Meybeck (FR 2 777 179; PTO-892) in view of Liu et al. (5,976,555, PTO-892), and

Suares et al. (US 5,914,116, PTO-1449 of record) is MAINTAINED. See under

response to arguments.

Claims 1, 2, 5-6, 9-10, and 13-16 are pending, and examined herein.

Claim Rejections - 35 USC § 103

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 6, 9, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (US 5,723,139, PTO-892 of record) and Gorbach (WO 98/56373, PTO-892), in view of Liu et al. (5,976,555, PTO-892 of record), and Suares et al. (US 5,914,116, PTO-1449 of record).

Granger et al. teach a skin conditioning composition comprising a compound selected from retinal or retinyl ester in an amount from about 0.001 % to about 10 %, in combination with a retinoid booster, polycyclic triterpene carboxylic acid, glycyrretinic acid in an amount from about 0.0001 % to about 50%. See column 1, line 42-column 3, line 39. It is further taught that the combination of retinal or a retinyl ester with a polycyclic triterpine carboxylic acid, glycyrretinic acid results in synergistic inhibition of keratinocyte differentiation. Retinoid boosters such as linoleic acid, arachidonic acid etc. are also disclosed as optional ingredients in the composition. See column 4, lines 29-38. The composition is applied to the skin for treating a skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots, acne, skin lightening etc. See column 12, claims 1-6. Granger et al. further disclose that the skin care composition therein is stored in a suitable container to form a skin care product. See column 11, EXAMPLE 6-7.

Granger et al. do not specifically teach the presence of phytoestrogens in the composition.

Granger et al. do not teach the storage of first composition comprising retinoid, and second composition comprising, glycyrretinic acid, and phytoestrogens, in separate compartments joined together.

Gorbach teaches that phytoestrogens such as genistein, daidzein, glycitin, equol, formononetin are useful for treating wrinkles, aging skin etc. Phytoestrogens are present in an amount of 1 and 40 mg per gram of base. See abstract; page 2, lines 7-15; column 6, claims 1-4.

Liu et al. teach that retinoids such as retinal, retinyl ester in skin care compositions are unstable due to oxidation or isomerization to non-efficacious chemical forms with the result that the amount of retinoid actually present to provide the beneficial effects is reduced in a short period of time. See column 2, lines 40-55. It is further taught that several stable compositions for skin care are supplied in two bottles (separating retinoids from other cosmetic ingredients), portions of which are mixed together just prior to use. See column 2, lines 54-62.

Suares et al. teaches a method for a skin treatment regime and product that includes a first composition containing at least one active and functioning to impart a benefit to skin, and a second composition that includes a second different active and imparts a benefit to skin (see abstract, in particular). Suares et al. teaches that the first and second compositions are stored in respective separate containers, which are joined together (see abstract and column 2, lines 1-14, in particular.) Suares et al. teaches that

Page 5

Art Unit: 1617

the two compositions are kept separate because single formulations often compromise the performance of the severally combined actives (see column 1, lines 15-25, in particular.) Accordingly, Suares et al. teachings provide a first composition in a first compartment, and a second composition in a second compartment, where the first and second compartments are joined together, as recited in claim 1. Those formulation taught by Suares et al. employ retinoid compositions useful for anti-wrinkle, and sunscreen dermal applications. See column 3, Table I; column 4, lines 59-64; TABLE IIII, column 8, and TABLE IV, column 9. Suares also teach a first composition, containing retinoid, and a second composition containing genistein, which are joined together. See TABLE IIII, column 8, and TABLE IV, column 9.

From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to add phytoestrogens such as genistein, diadzein to the compositions of Granger et al. since phytoestrogens are used to treat skin conditions such as wrinkled, photodamaged skin. It is generally considered a prima facia obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Granger, and Gorbach the instant claims contain compounds retinoids, glycyrretinic acid, and phytoestrogens used for improvement of skin appearance. *In re kirkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a two compartment system for separately storing retinal or retinyl ester in a first composition, and retinoid boosters such as glycyrretinic acid, linoleic acid, phosphatidylcholine and phytoestrogens in the second composition.

One having ordinary skill in the art would have been motivated at the time of invention to employ two compartments to separately store retinol or retinyl ester, and retinoid booster glycyrretinic acid and phytoestrogens because Liu et al. teach that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation. Moreover, several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together) based on the teachings of Liu. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and retinoid boosters, phytoestrogens in the second composition to keep retinol or retinyl ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Further, Suares et al. also employ a dual container system for multi composition use, and teaches the desirability of providing the two compartment product to maximize the effectiveness of the separate compositions, and teaches retinoids in one of the compositions. Those formulations taught by Suares et al employ retinoic acid in one compositions and phytoestrogen, genistein in another composition which are joined together useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been further motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherently present in the compositions. The skilled artisan would have seen the separate packaging teachings Suares et al. useful for individual application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Thus, the teachings of Liu in particular and Suares et al. have clearly provided the motivation to employ the separate compartments herein.

Regarding the recitation "wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", the recitation that the components of the second composition act as "boosting the first benefit", the recitation "wherein the retinoid boosters provide synergistic inhibition to transglutaminase", "the phytoestrogen being one that synergistically interacts with the retinoid", as recited in the claims, it is noted that the boosting activity, synergistic inhibition to transglutaminase, and inhibition of degradation of retinoic acid by a compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137

USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the compound, synergistic inhibition to transglutaminase, and inhibition of degradation of retinoic acid by the compound used therein.

Page 8

Further, the recitations "the first composition and second composition are retained separately and only come in contact after being applied simultaneously or consecutively", "wherein from about 1 to about 5 ml of the first composition and from about 1 to about 5 ml of the second composition are used" are considered a use of the composition and does not get patentable weight in composition claims. The teaching of Granger et al., Gorbach, in view of Liu et al., and Suares et al. obviously teach the claimed composition, thus the use is not given patentable weight.

Claims 1, 2, 5, 6, 9-10, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (US 5,723,139, PTO-892), Gorbach (WO 98/56373, PTO-892), and Meybeck (FR 2 777 179; PTO-892) in view of Liu et al. (5,976,555, PTO-892), and Suares et al. (US 5,914,116, PTO-1449 of record).

Granger et al., Gorbach, Liu et al., Suares et al. are as discussed above.

Granger et al. do not teach the presence of phosphatidylcholine in the composition.

Granger et al. do not teach the storage of first composition comprising retinoid, and second composition comprising retinoid boosters, phytoestrogens, in separate compartments joined together.

Meybeck et al. teach cosmetic and skin care compositions comprising retinoid, retinoid boosters such as 22-29 % of phosphatidyl choline, 0.1 % of glycyrretinic acid. These compositions can be used for treating skin conditions such as acne, aged skin, dry skin, etc. See page 3, lines 24-27; pages 8-9, Examples 1-2.; page 13, Example 11.

From the teachings of Meybeck et al., it would have been obvious to a person of ordinary skill in the art at the time of invention to add retinoid booster, phosphatidyl choline to the compositions of the Granger et al., since phosphatidyl choline is used to treat skin conditions such as dry skin, aged skin, acne etc. From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to add phytoestrogen such as genistein to the compositions of Granger et al. since phytoestrogens are used to treat skin conditions such as wrinkled, aged, and photodamaged skin. It is generally considered a prima facia obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Granger, Gorbach, and Meybeck et al., the instant claims contain compounds such as retinoids, phosphatidyl choline, glycyrretinic acid and phytoestrogens used for improvement of skin appearance. In re kirkohoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Art Unit: 1617

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a two compartment system for separately storing retinal or retinyl ester in a first composition, and retinoid boosters such as glycyrretinic acid, linoleic acid, phosphatidylcholine and phytoestrogens in the second composition.

One having ordinary skill in the art would have been motivated at the time of invention to employ two compartments to separately store retinol or retinyl ester, and retinoid booster glycyrretinic acid and phytoestrogens because Liu et al. teach that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation. Moreover, several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together). Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and retinoid boosters, phytoestrogens in the second composition to keep retinol or retinyl ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Further, Suares et al. also employ a dual container system for multi composition use, and teaches the desirability of providing the two compartment product to maximize the effectiveness of the separate compositions, and teaches retinoids in one of the compositions. Those formulations taught by Suares et al employ retinoic acid in one compositions, and phytoestrogen, genistein in another composition which are joined together useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been further motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherent in sequential application as set forth in Suares et al. claim 1. The skilled artisan would have seen the separate packaging teachings Suares et al. useful for individual application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Thus, the teachings of Liu in particular and Suares et al. have clearly provided the motivation to employ the separate compartments herein.

Regarding the recitation "wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", the recitation that the components of the second composition act as "boosting the first benefit", the recitation "wherein the retinoid boosters provide synergistic inhibition to transglutaminase", "the phytoestrogen being one that synergistically interacts with the retinoid" as recited in the claims, it is noted that the boosting activity, synergistic inhibition to transglutaminase and inhibition of degradation of retinoic acid by a compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137

USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the compound, and inhibition of degradation of retinoic acid by the compound used therein.

Further, the recitations "the first composition and second composition are retained separately and only come in contact after being applied simultaneously or consecutively", "wherein from about 1 to about 5 ml of the first composition and from about 1 to about 5 ml of the second composition are used" are considered a use of the composition and does not get patentable weight in composition claims. The teaching of Granger et al., Gorbach, in view of Liu et al., and Suares et al. obviously teach the claimed composition, thus the use is not given patentable weight.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive as discussed above, for the reasons already made of record in the previous office actions, and those found below.

Applicant argues that "There is no teaching whatsoever in the '555 reference or in any combination of references relied on by the Examiner that even remotely suggests the combination of specific retinoids with specific boosters and phytoestrogens as claimed in the present invention whereby the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid." These arguments have been considered, but not found persuasive. As discussed above regarding the recitation

"wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", it is noted that the boosting activity, synergistic inhibition to transglutaminase and inhibition of degradation of retinoic acid by a compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137 USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the compound, and inhibition of degradation of retinoic acid by the compound used therein.

Applicant argues that "The two component system as claimed in this invention, as well as the two preferred boosters as claimed in this invention are not even remotely suggested by the '555 reference which, again, employs a complicated oil-in-water emulsion system to stabilize certain retinoids." These arguments have been considered, but not found persuasive. It is pointed out that Liu et al. ('555) was employed for its teachings that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation. Several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients based on the teachings of Liu. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and retinoid boosters, phytoestrogens in the second composition to keep retinol or retinyl

ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Applicant argues that "the references fail to even remotely teach, suggest or disclose the need to separate phytoestrogens from retinoids. The present invention, again, is directed to two separate compositions with one intended to boost the benefit of the other after application. According to the present invention, the two compositions are intended to be applied simultaneously or consecutively, but are kept separately for stability reasons until application." These arguments have been considered, but not found persuasive. Granger et al. teach a skin conditioning composition comprising a compound selected from retinal or retinyl ester in an amount from about 0.001 % to about 10 %, in combination with a retinoid booster, polycyclic triterpene carboxylic acid, glycyrretinic acid in an amount from about 0.0001 % to about 50%. See column 1, line 42-column 3, line 39. It is further taught that the combination of retinal or a retinyl ester with a polycyclic triterpine carboxylic acid, glycyrretinic results in synergistic inhibition of keratinocyte differentiation. From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to employ phytoestrogens such as genistein, diadzein in combination with retinoids, and glycyrretinic taught by Granger for treating wrinkles. It is generally considered a prima facia obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. Suares et al. teaches that skin care compositions are kept separate because single

formulations often compromise the performance of the severally combined actives see column 1, lines 15-25, in particular. Further, Suares et al. teaches the employment of a dual container system that allows two compositions to be separated from one another, to maximize the effectiveness of the separate compositions, while also allowing for application of both compositions from a single product, and also provides an example wherein one composition contains retinoid, and a second composition contains genistein. Thus, it is considered that Suares et al. teaches that the compositions are isolated in each compartment so that the actives in each composition will not compromise the performance of one another, and thus teaches compartments in which the compositions are not degraded by each other and do not come in contact when being stored, as recited in claim 1. Liu et al. teaches that retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients. Accordingly, from the teachings of Suares et al., and Liu there is clear motivation to provide a composition comprising retinoid in a first compartment, and a second composition comprising retinoid booster and phytoestrogen in a second compartment, where the first and second compartments are joined together i.e retinoids are kept separate from other actives for stability reasons. The references '139, '373 render the claimed invention obvious in combination with '555, '116. Particularly, '116 teaches a stable skin care product that has two compositions that are isolated from each other in different compartments prior to use in the abstract and column 2; lines 1-14. More particularly, '116 teaches that the two compositions are kept separate because single

formulation often compromise the performance of the severally combined actives (see abstract and column 2; lines 1-14).

Applicant argues that "simply because the '179 reference appears to disclose the phosphatidylcholine and glycyrretinic acid somewhere in its disclosure clearly does not make it obvious for one of ordinary skill in the art to combine these materials with retinoids and with retinoid boosters in a dual compartment package and to derive the present invention. The Examiner, again, is not allowed to pick and choose elements from numerous references without there being a reason to combine the same." These arguments have been considered, but not found persuasive. Since the composition of '179 is also a cosmetic and skin care composition, one skilled in the art would find it obvious to use retinoid boosters such as 22-29 % of phosphatidyl choline, 0.1% of glycyrretinic acid of '179 because 22-29 % of phosphatidyl choline, 0.1% of glycyrretinic acid are used for treating skin conditions such as acne, and aged skin.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1617

shortened statutory period, will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Shobha Kantamneni whose telephone number is 571-

272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is

571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D

Patent Examiner

Art Unit :1617*

/SREENI PADMANABHAN/ Supervisory Patent Examiner, Art Unit 1617 Application/Control Number: 10/003,850

Page 18

Art Unit: 1617